Acquisition Support Strategy for the

Pump, Intravenous Infusion

NSN: 6515-01-550-5669

Manufacturer: Carefusion (formerly Cardinal/Alaris)
Model: Medsystem III with DLE (2865B)
Power: 6 Watts
Voltage: 110 VAC ± 20 Volts, 60 Hz
Package Weight: 35 lbs (16 kg)
Package: 5.8 cubic feet
LIN: P16161

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Acute Care Division
PMO Medical Devices
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Acquisition Strategy

The infusion pump is a commercial-off-the-shelf (COTS) used for the automatic delivery of precise and controlled amounts of intravenous fluids, both blood and crystalloids, to the sick and wounded. The PIV is not considered mission critical since there are alternative methods of administering intravenous fluids. Therefore, its loss may degrade, but will not prohibit medical mission accomplishment by the using organizations.

The infusion pump is authorized in the Combat Support Hospital (CSH, N301), Forward Surgical Team (FST, 267B), Patient Holding Squad (PHS, N308), Air Ambulance (AA, 257A), X-Ray Radiographic/Fluoroscopic (N307), Army Special Forces (SOF, 512A), Veterinary Animal Med-Surgical (912B), and Veterinary Small Animal Units (905B). The acquisition strategy is to purchase 12 for the N309 set, 8 for N308, 4 for 905B, N310, and 267B, 2 for N301 and 261A, and 1 for 257A, 912B, 512A, and N307.

The infusion pump is provisioned with all the necessary accessories and supplies. The system is purchased through Federal Supply Schedule (FSS) vendor Carefusion, part number MSIIISYS-SS. It has an item cost of $4,250.41 provisioned with necessary supplies ($3,899.91 for the pump alone). This item is OPA funded.

The life expectancy for the infusion pump is 8 years (TB MED 7). Operating costs[1] are $6,116 per year and maintenance costs are approximately $1,125 per year; therefore, the life cycle costs are calculated to be approximately $57,888 not including initial purchase costs.

NOTES:

1. These pumps may exist in Army inventory under NSN 6515-01-486-4310. The newer NSN cited in this document was obtained to include the bundled consumable administration supplies cited under the “Supply Support” section below.
2. On 20 January 2010, Carefusion announced the end of sales of this Medsystem III Infusion Pump to U.S. customers outside of the U.S. Government as of 1 March 2010. The cause is cited as an irreversible parts shortage. While Government sales continue at present, USAMMA is initiating action to find a replacement for this pump.

Clinical Application

The infusion pump is used by healthcare personnel to infuse fluid, medication and nutrients into the circulatory system. It provides three independent infusion channels for the delivery of a wide range of fluids from various containers, including syringes. The device also provides a secondary delivery of intermittent medications, fluid challenges, or loading doses from each channel. Each line can deliver a separate drug, helping to eliminate incompatibility and drug sequencing concerns.

[1] Consumable Supplies only

Integrated Logistics Support (ILS)

A. Maintenance Planning

1. Purpose: To provide a description of the requirements and tasks to be accomplished for achieving, restoring, or maintaining the operational capability of a system, or equipment. It covers the functions of preventive maintenance checks and services (PMCS) and associated schedule, periodic performance verifications and calibrations, and addresses the test, measurement, and diagnostic equipment (TMDE) used to care for the end item. Lastly, it addresses the maintenance levels of operations and those responsibilities of maintenance personnel therein.

2. Responsibilities: Biomedical and support maintenance can be performed by personnel holding the military occupational specialty 68-A, original equipment manufacturer (OEM), or OEM-trained civilian technicians. Reference material to be used by the maintenance personnel includes, but is not limited to manufacturers, operators, and/or service literature.

3. Maintenance Procedures.

    a. Field Support Maintenance: This item has been assigned a maintenance recoverability code (MRC) "O." The system can be repaired and disposed of at the unit level. There are no special tools or procedures indicated that would hinder the unit maintainer from completely repairing the unit. See inspection procedures below, Section 4b.

    b. Sustainment Support Maintenance: The sustainment level repair for this item will be at MEDLOG Company, which includes replacing subassemblies, rebuilding, and providing field support maintenance for medical units that do not have organic maintenance support. Use of medical equipment standby equipment program (MEDSTEP) materiel will be utilized when non-mission capable (NMC) days exceed 3 days or the unit's assets fall below 75% availability.

    c. Depot-level Maintenance: Depot-level maintenance for the system will be used when the system requires overhaul, refurbishment or a safety modification.

    d. OEM Level Maintenance: Carefusion provides parts support for this pump, but is discontinuing repair services as part of its end of sales.

4. Inspection Procedures:

    a. This item has been assigned a type item code (TIC) "C." This means prior to being issued from an USAMMA Maintenance Operations Division, this item will have a technical inspection to ensure it was

received from the vendor according to the contract and that it functions within the guidelines set by the manufacturer and USAMMA.

b. The system is to be inspected on a scheduled basis in accordance with the published 10/20 PMCS or the manufacturer's literature.

5. Tools and TMDE required for inspection:
   a. Tool Kit, Medical Equipment, 5180-00-117-3414
   b. Tool Set, Medical Equipment Maintenance Unit, 5180-01-483-1431
   c. IV Pump Analyzer, 6515-01-536-2122
   d. Oscilloscope DHH, 6625-01-448-9577
   e. Stop Watch, 6645-01-106-4302 (or other suitable)
   f. Laptop Computer, 7010-01-502-5490

6. 10/20 Standards and MAC – See Appendix D

7. MEDSTEP:

   a. MEDSTEP will be maintained at the MEDLOG Company or at one of the USAMMA Maintenance Operations Divisions.

   b. MEDSTEP requirements will be based on two each per three CSHs in the support area. That number may be subject to validation based on the condition of the equipment.

   c. MEDSTEP requirements will be reevaluated on an annual basis. The support MEDLOG must be in possession of MEDSTEP in order to affect quick turnaround.

8. Repair Parts/Spare Parts Listing: Repair parts were determined using OEM and/or maintenance historical data. Spare parts can be obtained from existing stock or vendors. Spare parts packages will not be included with each system. Recommended spare parts include, but are not limited to:

Item No	Part or Accessory Description	Part or Accessory Number	Basic Issue	Operator[2]	Repairer
1	Battery	93-0415-P	0	0	0
2	Motor Kit	2860760	0	0	0

[2] X = Operator or Repairer can use this part to fix the system

9. Annual Man-hour Requirements

    a. Field Support

(1)	Repair:	5.0 hours
(2)	PM:	1.4 hours
(3)	Safety:	6.0 hours
(4)	Calibration:	3.0 hours
(5)	TOTAL:	15.4 hours

    b. Sustainment Support: Repair: 5.5 hours

10. Warranty Control Procedures. The infusion pump comes with a 1 year manufacturer's warranty. The warranty includes parts and labor. When warranty service is needed, Carefusion may be contacted at 3750 Torrey View Court, San Diego, CA 92130, Telephone (858) 617-2000.

11. It is recommended that this item be designated DA 2406 readiness reportable.

12. SPECIAL NOTE: The PIV tubing contains a cassette that provides protection from free-flow conditions.

B. Training and Training Support

1. Maintainer: No additional training is required above the standard training received by the 68A at the biomedical maintenance course at the DOD Biomedical Equipment Training School.

2. Operator: All training requirements will be IAW the system training plan that was approved 6 June 2003. New Equipment Training (NET) may be required, as well as instructor and key personnel training during any testing and fielding phases of development. As a minimum, NET will be required for the instructor staffs at operator and maintainer MOS producing courses.

C. Manpower and Personnel

The fielding of the infusion pump will have no impact upon manpower or personnel structure. Operator and maintainer actions will be performed by the same soldiers currently performing similar functions. The total number of authorized operators or maintainers will neither increase nor decrease in the manpower/force structure area. The operator, MOS 66N (Registered Nurse), MOS 60N (Anesthesiologist), 66F (Nurse Anesthetist), 68W (Health Care Specialist), 68T (Animal Care Specialist), or 68W2F (Flight Medic), will perform operator checks and services. Field level maintenance will be performed by Medical Equipment Repairers, MOS 68A, assigned to the divisional medical companies and combat support hospitals. Sustainment level maintenance will be performed by the MOS 68A or civilian assigned to the Medical Logistics Companies.

D. Supply Support

Specific COTS support equipment and consumable items are required for the operation of the infusion pump. These are available through standard supply sources which are predominantly commercial manufacturers, vendors and distributors cataloged in the Medical Supply Information Logistics System (MEDSILS) and available via the DSCP ECAT system. It is the responsibility of the Services to order these items via established logistics channels within DOD supply system.

E. Support Equipment

This infusion pump can be supported with supplies which can be ordered from Carefusion via the DSCP ECAT system (see table and pictures).

Support NSN	Mfg Part #	Support Nomenclature (Long)
6515-01-452-3445	28034E	Administration Set, Main Stream
6515-01-416-4032	72213N	Administration Set, Piggyback

Administrative Set, Main Stream Line (28034E)
NSN 6515-01-452-3445 (50 PG)

Administrative Set Piggy Back (72213N)
NSN 6515-01-416-4032 (100 PG)

F. Technical Data

1. Service Manual: MedSystem III Multi-Channel Infusion Pump Service Manual, May 1995, P/N 2863012. This is available in PDF or IETM via CD by going to the USAMMA website (http://www.usamma.army.mil/med_equip_lit_cdroms.cfm) and following the instructions or by calling DSN 343-4379 or commercial 301-619-4379.

This manual is supplemented by Service Bulletins located on the USAMMA CDs and on the Carefusion web site. A password to the Carefusion site may be obtained by calling Carefusion. See section A.

2. Operator's Manuals: Medsystem III Infusion System with Dose Rate Calculation and Drug List Editor, Directions for Use. P/N 10551005.

G. Computer Resources Support

No computer resources are required for use of the system in day-to-day operation. A computer and interface cable are used by the medical equipment repairer to download drug dose software from a CD to prepare the pump for first use.

H. Facilities

There are no unique facilities, shelter, or environmental compliance requirements. Warehouse storage is required prior to deployment to a unit.

I. Packaging, Handling, Storage and Transportation

The infusion pump is packaged in a fiberboard container. It will be transported by vehicles organic to using organizations or by other transportation assets within the theater. There are no strategic lift constraints associated with this system. When transported (per MIL STD 1472), the system may be carried by one person. All support items are non-deteriorative.

INFUSION PUMP CHARACTERISTICS

Storage temperature	-4°F to 131°F
Operating temperature	50°F to 104°F
Relative humidity	Not specified
Dimensions (L x W x H), in	6 x 2.1 x 7.9
Weight (lb)	5.1

J. Design Interface

The infusion pump will interface with the electrical distribution system at the using organization.

K. Requisition / Supply

1. The infusion pump is a non-stocked centrally procured item. The system will be provided during an initial fielding or sustainment fielding. Or if requested from the unit, procurement will be initiated only after receipt of a requisition.

2. AAC Code = J, which denotes NOT STOCKED - CENTRALLY PROCURED (non-stocked items) - IMM/Service centrally managed but not-stocked item. Procurement will be initiated only after receipt of a requisition.

3. ARC Code = N, which denotes Class VIII items valued at $500 or more that retain their original identity and are not consumed in use and non-maintenance significant medical furniture items valued at $1,000 or more.

4. TIC Code = C, which denotes critical medical equipment requiring technical Inspection.

5. Resupply items for this product are noted in the Supply Support and Support Equipment section.

Appendix A – Market Analysis

N/A

Appendix B – Standardization Efforts

In early 2008, Defense Medical Standardization Board developed and coordinated the following set of essential characteristics and system attributes for infusion pumps.

Infusion Pump Key Performance Parameters and Essential Characteristics

Essential Characteristics		THRESHOLD	OBJECTIVE
Multi-channel = three or more channels for infusion		3 Channels	5 Channels
Dose Calculator: with capabilities to display: medication name, dose (mcg/kg/min, u/hr, etc and actual rate per hour.		FDA Standard	FDA Standard
Rapid fluid infuser capable		6 L/hr	T=O
Drug calculations and library of medications. Ability to report similar to current triple channel pump. Record/time stamp changes and titration. Ability to utilize multiple factors (unit, concentration and time based) and integrated with central processing unit for documenting infusions		Yes	DOSE error reduction system
Capable of fluid/blood warming		37.5oC	40oC
Vented bubble detector and removal		Yes	T=O
Infusion Pump/Fluid Delivery System Attributes			
Attribute	**Priority (On a Scale of 1 to 4)**	**Threshold**	**Objective**
Portable - </= current Alaris MedSystem III= Height 7.9 inches, Width 6 inches, Depth 2.1 inches, Weight 5.1 lbs	1	Yes	T=O
Battery Life Meets or Exceeds 6 Hours	1	Yes	T=O
Battery is Rechargeable	1	Yes	T=O
Meets Airworthiness Certification	1	Yes	T=O
AC Power - 110+ Volt Compatible	1	Yes	T=O
Frequency - 50-60Hz or Higher	1	Yes	T=O
Free-Flow Protection	1	Yes	T=O
Audible and visual alarms present for the following categories: Air in line, flow error, low battery, occlusion, infusion complete/change bag	1	Yes	T=O
Piggybacking	1	Yes	T=O
Durability: Able to pass Drop Testing	1	Yes	T=O
Needleless Infusion Capability	1	Yes	T=O
Readability present utilizing Night Vision Goggles	1	Yes	T=O
Total Infusion Volume Meets or Exceeds 1-9999mL	1	Yes	T=O
Infusion Rate Meets or Exceeds 0.1-999mL/hr	1	Yes	T=O
Vented Bubble Detector Present	1	Yes	T=O
Capable of centralized monitoring via USB Port	1	Yes	T=O
Cleaned via Standard Procedure Without Degradation	1	Yes	T=O
Simple to Operate: Machine prompts are clear, concise and simple to change from each mode of operation	1	Yes	T=O
Software Upgrades Available from Manufacturer	1	Yes	T=O
Flow Error at or below 5%	1	Yes	T=O
Labels and Markings Permanently Displayed on Device	2	Yes	T=O
Record: Patient measurements and interventions. Cumulative total fluid received (infused, and net volumes) Date/Time Stamp, Patient measurements and interventions (electronic record)	1	Yes	T=O
Using needleless standard safety	1	Yes	T=O
Free-flow protection.	1	Yes	T=O
Industry standard alarms - auditory and visual. Low battery alarms	1	Yes	T=O

Attribute	Priority (On a Scale of 1 to 4)	Threshold	Objective
Control: Decision assist algorithm based on provider input parameters	3	Yes	T=O
PCA system compatibility and capable on at least one channel with remote PCA	3	Yes	T=O
Control: Rate and volume of crystalloids, colloids, and blood products. Closed-loop algorithms control infusion rate and volume based on endpoint (blood pressure, UOP, hemoglobin, or other measure (s) TBD)	4	Yes	T=O
Epidural administration of anesthetic and analgesic drugs capability	3	Yes	T=O
Incorporate a "Syringe Holder" (up to three 20-60ml syringes simultaneous use capability) for use as the container for IV fluid to be infused for pediatrics.	4	Yes	T=O

Appendix C – Testing and Airworthiness

The MedSystem III is fully authorized for operation in the following helicopters: UH-60A, UH-60L, UH-60Q, and HH-60L, Reference Airworthiness Release (AWR) for MEDEVAC H-60 Helicopters Equipped with Patient Movement Items (PMI) (AWR 1330), 8 September 2006.

Appendix D – 10/20 Standards and MAC Chart

10/20 Standards
Operator's Preventive Maintenance Checks and Services

6515-01-550-5669
Pump, Intravenous Infusion

B-Before Operation, D-During Operation, A-After Operation, Q-Quarterly, and S-Semiannually

Item No	Interval	Item to be Inspected and Procedure	Is Not Mission Capable If:
1	S	**Inspection**	
		a. Conduct an inventory to ensure that the following items are in the storage/shipping container. Multi-Channel Infusion Pump Administrative Set, Mainstream Line Administrative Set; Piggy Back (Both Shipped in Separate Boxes) Battery Pack Operator's manual	Missing components or accessories that would prevent the full operation of the pump.
		b. Check for signs of damage to the outside of the pump housing for example holes and scratches.	Cracked display screen
		c. Check the rotating latch and adjustable pole clamp for easy of movement and 360 degree rotation.	Clamp or latch will not move. Clamp and latch are broken.
		d. Check display screen for scratches and Discoloration.	Screen is damaged
2	S	**Functional Check-out Procedures** a. Turn on Pump	
		(1) Press the on/off button: Upon start-up the instrument performs an automatic self-test. Listen for a beep this indicates that the audio alarm transducer is functioning. The instrument information page is momentarily displayed. The standard display page is displayed.	A fault is indicated.

Operator's Preventive Maintenance Checks and Services

6515-01-550-5669
Pump, Intravenous Infusion

B-Before Operation, D-During Operation, A-After Operation, Q-Quarterly, and S-Semiannually

Item No	Interval	Item to be Inspected and Procedure	Is Not Mission Capable If:
		(2) Check audio and keypad operation by ensuring there is a soft beep for each key pressed. (3) Press any key and ensure the LCD backlight turns on. b. AC Power test (1) Turn on the instrument without the AC adapter attached. Install a primed cassette in each pump channel. Start all channels. Verify the green LED on each channel blinks during operation. Attach the AC adapter to the pump. Verify that the instrument beeps three times when the connector is properly installed. Verify that the green plug shaped light on the side connector panel is lit. c. Check to ensure that the four soft-keys are working by selecting a function that is controlled by that key for example adjusting the flow rate or setting the contrast of the display. d. Push the on/off instrument key to off.	The LED on any channel does not light. The plug shaped light does not flicker when the connector is wiggled.

Repairer's Preventive Maintenance Checks and Services

6515-01-550-5669
Pump, Intravenous Infusion

[M-Monthly, Q-Quarterly, S-Semiannually, and A-Annually]

Item No	Interval	Item to be Inspected and Procedure	Is Not Mission Capable If:
1	S	**Inspection**	
		a. Conduct an inventory to ensure that the following items are in the storage/shipping container. Multi-Channel Infusion Pump Administrative Set Main Stream Line (Shipped Separately) Battery Pack Operator's manual Service manual	Missing components or accessories that would prevent the full operation of the pump.
		b. Perform the operator's PMCS inspection as prescribed in the -10 procedure.	Cracked display screen
2	S	**Cleaning Procedure**	
		Note: do not use organic solvents, ammonia, or ammonium based agents for cleaning.	
		a. Clean the exterior surface of the instrument using a damp warm water cloth with a mild nonabrasive standard hospital disinfectant or a detergent.	
		b. Clean the lower housing and pump assembly by removing the lower plastic housing by depressing the four black release tabs in the upper corners. Next pull straight down. Use a soft bristled brush to clean the pump latch mechanism and linkage.	
		c. Clean the air in line sensor tubing by wiping the tubing recess with a nonabrasive cloth, pad or swab moistened with isopropyl alcohol.	

Repairer's Preventive Maintenance Checks and Services

6515-01-550-5669
Pump, Intravenous Infusion

[M-Monthly, Q-Quarterly, S-Semiannually, and A-Annually]

Item No	Interval	Item to be Inspected and Procedure	Is Not Mission Capable If:
		d. Clean the valve actuators with a nonabrasive, lint free cloth and mild non-staining disinfectant or detergent being careful not to bend the valve or tear the actuator seal.	
3	A	**Annual Maintenance** Retrieve the Event Log by following the steps in the maintenance manual 4.2.c Checking Memory Backup Battery by following the steps in the maintenance manual section 4.2.d Verify proper Software Version serial number and customized setting by following the steps in the maintenance manual section 4.2.e	
4	S	**Calibration** Perform the calibration procedure as outlined in Chapter 5 of the maintenance manual for the following test : Patient –side occlusion Fluid –side occlusion Rate Cassette/latch sensor	Failed any of the tests

Maintenance Allocation Chart

6515-01-550-5669
Pump, Intravenous Infusion

[FS – Operator, Crew; SS – Unit Maintenance or Depot Maintenance]

(1) Group #	(2) Assembly Group	(3) Maintenance Function	(4) Maintenance Level	(5) Tools and TMDE Code	(6) Remarks
1	Infusion Pump	Calibration Test Service	FS FS FS, SS	01, 11, 21, 20	
2	Battery Pack Assembly	Inspect, Replace	FS	20	
3	Audio /Connector PCBA Kit	Replace	SS	20, 21	
4	Main Electronics Assembly Kit	Replace	SS	20, 21	
5	Display Module	Repair or Replace	SS	01, 02	
6	Power PCBA Kit	Inspect, Replace	SS	01, 20, 21	
7	Universal Pole Clamp	Inspect	FS	01	
8	Drive Module Kit	Inspect, Replace	FS SS	01, 21	
9	Housing Componets	Inspect, Replace	FS	01	
10	Sensor Components	Inspect, Replace	FS	01	
11	Memory Backup Battery Kit	Inspect	FS	01, 20	

Comment [kmh1]: Line underneath to separate

Maintenance Allocation Chart

6515-01-550-5669
Pump, Intravenous Infusion

[FS – Operator, Crew; SS – Unit Maintenance or Depot Maintenance]

(1) **Group #**	(2) **Assembly Group**	(3) **Maintenance Function**	(4) **Maintenance Level**	(5) **Tools and TMDE Code**	(6) **Remarks**
12	Pump Latch Assembly Kit	Inspect Replace	SS FS	01, 21	
13	Infusion Pump	Rebuild	D	01, 11, 20, 21,	

Comment [kmh1]: Line underneath to separate

Appendix E
Tools and TMDE Code Listing for Maintenance Allocation Charts

RefCode	Item / Nomenclature	LIN	NSN	Model
01	Tool Kit, Medical Equipment Maintenance Repairer	W45334	5180-00-611-7923	Individual GSA Item
02	Tool Set, Medical Equipment Maintenance Unit Level	W45197	5180-01-483-1431	GSA
03	Shop Set Med Log Medical Equipment Maintenance	T24386	6545-01-555-8683.	Med Log Co
04				
05	X-ray Calibration & Verification System	CO5856	6525-01-502-0504	UNFORS 710-L
06	Gas Flow Analyzer	C61523	6515-01-541-2864	VT-Plus
07	Anesthetic Gas Analyzer	A00098/	6630-01-530-7959 6630-01-487-6987	Riken FI-21 Riken 1902D
09				
10	Analyzer NIBP	A27104	6515-01-449-1423	Cufflink
11	IV Pump Analyzer	J24245	6515-01-449-2331 6515-01-479-2355	IPT-1 IDA4P/3 Depot Only
12	Defibrillator Analyzer TPA Tester Defibrillator	A83433	6515-01-575-2825 6515-01-449-1420	Impulse 7000 Impulse 4000
13	Counter, Electronic Digital	C19266	6515-01-406-7390	AN/USM-459A
14				
15	Simulator, Medical Function Simulator, Medical Function	S56720	6515-01-548-3352 6625-01-298-3830	MPS450 Army Medical Kit 215M
16	Signal Generator	S48323	6625-01-276-9421	SG-1288/G
17	Computer, Laptop	N/A	7010-01-502-5490	Various
18	Foot Candle Meter	M38443	6695-01-574-8935	12421
19	Thermometer		6685-01-292-7873	51-II Single Channel
20	Multimeter, AN/PSM-45A Multimeter, AN/USM-486	M60449 M23954	6625-01-265-6000 6625-01-145-2430	27/FM 8050A CTA
21	Oscilloscope, Digital Medical Oscilloscope	P43667	6625-01-560-1673 6625-01-513-7811	199B 199C
22	Meter, Ultrasound Therapy Wattmeter	R95994	6695-01-575-6270	Power
24	Simulator, Pulse Oximetry	S57953	6515-01-541-0432	INDEX 2XLFE
25	Tachometer Digital Medical Equipment	T07421	6625-01-550-3339	1726
26				
27				
28	Test Set, Electrosurgical	T90883	6515-01-564-8554	QA-ES II
29	Tester, Current Leakage	T61791	6625-01-577-6744 6625-01-207-8270	ESA612 232D
31	Tester, Ventilator	T05633/	6515-01-449-1421	Pneuview 360001

Appendix F - Reference

N/A

Appendix G
Cost Analysis

Operational Cost: Based on usage of consumables only. 4 Mainstream ($4.95 each) and 4 piggyback lines ($1.03 each) per day; pump used 70% of days during product life cycle.

Maintenance cost: The maintainer will estimate the yearly maintenance cost.

Total life cycle cost not including purchase: Add both the operational cost and the maintenance cost per year basis. Multiply this number by the estimated operational life per TBMED7. This is the total life cycle cost.

Calculations:
Consumable usage per year: 4 * $5.98 * 365 * 0.7 = $6111
Cost of consumables per year: $6111
Maintenance cost per year: $1125
TBMED7: 8 years

Total cost: $57,888